REMARKS

Claims 18, 21, 36 and 37 were presented for examination. Claims 18, 21, 36 and 37 were rejected.

Rejections Under 35 U.S.C. § 103(a)

Claims 18, 21, 36 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Svenson et al in view of Eigler et al. Applicant respectfully traverses.

Claim 21 recites a transseptal apparatus for locating the fossa ovalis in a patient and performing a transseptal puncture of the fossa ovalis. The apparatus comprises, in part, a catheter for use in transseptal punctures. The catheter comprises a hollow lumen, a first electrode positioned at the distal end of the catheter and a second electrode positioned on the catheter and spaced proximally from the first electrode. The apparatus also comprises a recording device that generates unipolar electrograms from the electrophysical activity of the interatrial septum sensed by the first electrode and bipolar electrograms from the electrophysical activity of the interatrial septum sensed by both the first electrode and the second electrode.

Svenson discloses a process and apparatus for mapping of tachyarrhythmia. However, Svenson fails to disclose fail to disclose the generation of unipolar electrograms by a first electrode (i.e., the electrode positioned at the distal end of the catheter) and the generation of bipolar electrograms by both the first electrode and a second electrode (i.e., the electrode positioned proximally from the first electrode along the catheter). Instead, Svenson discloses bipolar electrodes embedded in cylindrical cavities at the distal end of the polymer member (Col.4, lines 29-30). The distal bipolar electrodes, in Svenson, sense endocardial potentials and QRS signals (Abstract). Svenson does disclose a unipolar electrode embedded into recesses of the member at a spaced distance from the bipolar electrodes (Col. 2, lines 33-35; Col. 4 lines 34-37). This unipolar electrode senses intercardic potential and EKG signals (Abstract). Svenson discloses using the distal bipolar electrodes to map areas of ventricular techycardia within the heart (Col. 5, lines 39-45) while the unipolar electrode provides EKG signals (Abstract).

In contrast, the claims recite at least a unipolar electrode located at the distal end of the catheter for sensing electrophysical activity of the interatrial septum in order to map the location

of the fossa ovalis (see page 13, lines 14-22 of the Specification). A second electrode is spaced proximally from the first electrode. The first and second electrodes form a bipolar electrode pair for addition bipolar electrophysical sensing (see page 14, lines 9-18 and lines 29-33). On page 13, lines 24-32 and page 15, lines 6-19, the dangers of strictly using only bipolar electrograms to map the fossa ovalis are stated. As mentioned above, Svenson discloses using the distal bipolar electrodes to map areas of ventricular techycardia within the heart (Col. 5, lines 39-45), not the spaced apart unipolar electrode. In addition, the specification on page 16, lines 23-34 recites the benefits of the use of unipolar signals to locate the fossa ovalis. There is no teaching or suggestion that the Svenson bipolar electrodes located at the distal end of a single catheter have the capability to serve as unipolar electrodes for the generation of unipolar electrograms. Nor is there any teaching or motivation that the Svenson unipolar electrode and the distal tip bipolar electrodes can form a bipolar electrode pair as claimed.

The Examiner admits that Svenson fails to teach a transseptal needle and sensors of electrophysical activity of an interatrial septum and cites Eigler in this regard. However, Eigler fails to remedy the deficiencies of Svenson because Eigler does not disclose a first electrode and a second electrode that are both positioned on a catheter and that provide electrophysical activity signals of the interatrial septum to a recording device that generates unipolar electrograms from the electrophysical activity of the interatrial septum sensed by the first electrode and bipolar electrograms from the electrophysical activity of the interatrial septum sensed by both the first electrode and the second electrode. Instead, Eigler discloses a pressure transducer that is permanently implanted into the left atrium for the constant monitoring and notification of fluid pressure levels in the left atrium (Col. 2, lines 8-12; Col. 3, lines 18-21). In addition, Eigler discloses piercing the interatrial septum with a Brockenbrough catheter (Col. 4, lines 2-18). However, Eigler is silent regarding the generation of unipolar and bipolar electrograms from the first and second electrodes on the catheter in order to locate the fossa ovalis as the interatrial septum site to be pierced. Therefore, neither Svenson nor Eigler disclose these limitations in the claims.

Nor does the hypothetical combination of Svenson and Eigler suggest or teach a first

electrode and a second electrode on a catheter that provide electrophysical activity signals of the interatrial septum to a recording device for the generation of unipolar electrograms from the electrophysical activity of the interatrial septum sensed by the first electrode and bipolar electrograms from the electrophysical activity of the interatrial septum sensed by both the first electrode and the second electrode. Because the hypothetical combination of Svenson and Eigler does not suggest or teach all the limitations of the claims, Applicant believes that claim 21 is patentable over the prior art and requests the withdrawal of the rejection to claim 21.

Claims 19 depends from the independent claim 21. This dependent claim is patentable for the same reasons as presented above with respect to claim 19 from which it depends. Therefore, Applicant asserts that claim 19 is also patentable over the prior art and requests the withdrawal of the rejection thereof.

Claim 36 recites a transseptal apparatus for locating the fossa ovalis in a patient and performing a transseptal puncture of the fossa ovalis. The apparatus comprises, in part, a location signal generator for providing a location signal to at least one of the electrodes in order to locate the fossa ovalis. In addition, the transseptal apparatus is configured such that a user may identify the fossa ovalis of patient on the basis of at least one of the following parameters: unipolar voltage reduction; signal fractionation; broadened signal; reduced signal slew rate; reduced local myocardial impedance; increased phase angle; and increased pacing threshold.

As discussed above, Svenson discloses a process and apparatus for mapping of tachyarrhythmia. However, Svenson fails to disclose a location signal generator for providing a location signal, or impulse, to at least one of the electrodes on the catheter in order to locate the fossa ovalis by measuring, for example, impedance or the pacing threshold of the interatrial septum. In fact, there is no mention at all of a location signal generator in Svenson. In addition, Svenson is completely silent to the use of impedance or pacing threshold measurements in locating the fossa ovalis.

The Examiner admits that Svenson fails to teach a transseptal needle and sensors of electrophysical activity of an interatrial septum and cites Eigler. However, Eigler fails to remedy the deficiencies of Svenson because Eigler does not disclose a location signal generator for

providing a location signal, or impulse, to at least one of the electrodes in order to locate the fossa ovalis by measuring, for example, impedance or the pacing threshold of the interatrial septum. In addition, Eigler is also completely silent to the use of impedance or pacing threshold measurements in locating the fossa ovalis. Therefore, neither Svenson nor Eigler disclose these limitations in the claims.

Nor does the hypothetical combination of Svenson and Eigler suggest or teach a location signal generator for providing a location signal, or impulse, to at least one of the electrodes in order to locate the fossa ovalis by measuring, for example, impedance or the pacing threshold of the interatrial septum. Because the hypothetical combination of Svenson and Eigler does not suggest or teach all the limitations of the claims, Applicant believes claim 36 is also patentable over the prior art, and requests the withdrawal of the rejection of claims 36.

Claim 37 depends from the independent claim 36. This dependent claim is patentable for the same reasons as presented above with respect to the claim from which it depends. Therefore, Applicant asserts that claim 37 is also patentable over the prior art and requests the withdrawal of the rejection thereof.

Conclusion

For the above reasons, the Applicant respectfully submits that the above claims represent allowable subject matter. The Examiner is encouraged to contact the undersigned to resolve

efficiently any formal matters or to discuss any aspects of the application or of this response.

Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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